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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/704,159 08/28/96 WILLIAMS J OPHD-02304

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HM22/0226

EXAMINER

LI,B

ART UNIT

PAPER NUMBER

1648

25

DATE MAILED:

02/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/704,159	Applicant(s) WILLIAMS ET AL.	
	Examiner Bao Qun Li	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-109 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 42-109 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

The supplemental amendment is acknowledged. The claims 1-41 are canceled and new claims 42-109 are added, therefore, claims 42-109 are pending before the examiner.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 42-45, 54-65, and 79-109 drawn to a soluble recombinant protein, its associated fusion protein and a composition comprising the soluble protein, classified in class 424, subclass 247.1, class 435, subclass 252.7.
- II. Claims 46-53, 66-78 drawn to a host cell expressing a recombinant protein encoded by clostridium botulinum toxin classified in class 435, subclass 246.

If either group I or II is elected, further restriction is required under 35 U.S.C. 121:

- (i). The recombinant protein is clostridium botulinum type A toxin;
- (ii). The recombinant protein is clostridium botulinum type B toxin;
- (iii). The recombinant protein clostridium botulinum type C1 toxin;
- (iv). The recombinant protein clostridium botulinum type D toxin;
- (v). The recombinant protein clostridium botulinum type E toxin;
- (vi). The recombinant protein clostridium botulinum type F toxin;
- (vii). The recombinant protein clostridium botulinum type G toxin;
- (viii). The recombinant protein encoded by SEQ NO. 28;
- (ix). The recombinant protein encoded by SEQ NO. 23;
- (x). The recombinant protein encoded by SEQ NO. 40;
- (xi). The recombinant protein encoded by SEQ NO. 42;
- (xii). The recombinant protein encoded by SEQ NO. 46;
- (xiii). The recombinant protein encoded by SEQ NO. 60;
- (xiv). The recombinant protein encoded by SEQ NO. 66;
- (xv). The recombinant protein encoded by SEQ NO. 50;
- (xvi). The recombinant protein encoded by SEQ NO. 52;
- (xvii). The recombinant protein encoded by SEQ NO. 71;
- (xviii). The recombinant protein encoded by SEQ NO. 77;

- (ixx). The recombinant protein encoded by SEQ NO. 68;
- (xx). The recombinant protein encoded by SEQ NO. 73
- (xxi). The recombinant protein encoded by SEQ NO. 79.
- (xxii). The recombinant protein encoded by SEQ NO. 44.
- (xxiii). The recombinant protein encoded by SEQ NO. 62.
- (xxiv). The recombinant protein encoded by SEQ NO. 54.
- (xxv). The recombinant protein encoded by SEQ NO. 56.
- (xxvi). The recombinant protein encoded by SEQ NO. 26.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the protein in groups I and cell in group II are structurally distinct subject matter and they act in different modes as well as exhibit different biological functions. For example the cells in group II can be used for producing antibody or infection with different viruses, whereas the proteins in group I can be used for inducing immune response and they can also be made by different mechanism such as chemical synthesis or purification from the native resources. Therefore, they are not related.

Inventions (i) to (xxvi) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the protein in different groups of the invention is structurally divergent peptide or polypeptide, e.g. the protein in group (i) and protein in group (ii), has different molecular structure and it exhibits different biological feature in turn of inducing a different immune response in the host. Therefore, different groups of the inventions are unrelated.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 1648

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

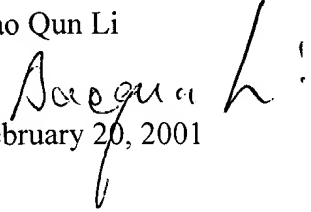
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:30 Am to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li


February 20, 2001


JAMES HOUSEL 2/23/01
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600